U.S. House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion
Tuesday, May 8, 2018
10:00 AM, Rayburn 2123

Purpose
The purpose of this hearing is to investigate the role of wholesale drug distribution and diversion in the opioid epidemic in the U.S. Specifically, the hearing will examine whether any breakdowns occurred in the closed system for controlled substance distribution, established under the Controlled Substances Act (CSA), resulting in massive amounts of prescription opioids being shipped to small-town pharmacies in rural West Virginia while the opioid crisis continued to worsen throughout the U.S., but particularly in West Virginia.

Members Present
Chairman Walden, Ranking Member Pallone, Subcommittee Chairman Harper, Subcommittee Ranking Member DeGette, Vice Chairman Griffith

Reps. Barton, Castor, Schakowsky, Burgess, Tonko, Brooks, Ruiz, Walberg, Walters, Carter, Costello, Blackburn, Lance, McKinley, Johnson, Bilirakis,

Witnesses
Mr. George Barrett
Executive Chairman of the Board, Cardinal Health, Inc.

Mr. Steven Collis
Chairman, President, and CEO, AmerisourceBergen Corporation

Mr. John Hammergren
Chairman, President, and CEO, McKesson Corporation

Dr. Joseph Mastandrea
Chairman of the Board, Miami-Luken, Inc.

Mr. J. Christopher Smith
Former President and CEO, H.D. Smith Wholesale Drug Company

Opening Statements
Subcommittee Chairman Harper said that the launch of this investigation one year ago was spurred by reports of over-distribution of opioids to small-town pharmacies in West Virginia. He said that Cardinal Health, Amerisource Bergen, and McKesson shipped nearly 9 million opioids to West Virginia in the last few years.

Subcommittee Ranking Member DeGette said that the goal of today' hearing to find out what these companies knew about the rise of an opioid epidemic and when they knew it. At the end of the day, whatever systems in place by distributors weren't effective and didn't prevent damage from happening to these communities. She shared examples of small towns (pop. 400 or less typically) being sent opioids in the millions.

Chairman Walden said the Committee proceeds on two tracks: one, to address legislatively the opioid crisis, and two, to continue this investigation. He recounted DEA enforcement issues faced by McKesson et. al. and the fines they had to pay as a result. The question today is if distributors have reached DEA compliant distribution programs. It's not sufficient just to blame the DEA. The distributors have shared responsibility and unique resources; they are on the frontlines of this investigation.

Ranking Member Pallone said the distributors who provided these pills to small-town pharmacies didn't submit suspicious order reports to the DEA and their files are sparse, showing they didn't particularly care to investigate. It is the distributor's responsibility to know their customers. He listed a slate of factors that contributed to this epidemic, including doctors who shirked their responsibilities, state/federal regulations that fell through, and lack of oversight from distributors.

Witness Testimony

Dr. Mastandrea gave background on his company. It wasn't until the DEA issues subpoenas that the company realized there were compliance issues. The company then hired and worked with a lawyer who formerly worked at DEA to fix their compliance issue. As a result of new management's enhanced compliance efforts, Miami-Luken terminated its relationship with multiple customers, many of whom are still in business purchasing from other sources. Since 2014, we have reduced the sale of Oxycodone by 61%, and the sale of Hydrocodone by 50%. It is our understanding that former management took what they believed to be sufficient steps at the time, believing that State Medical Boards and Pharmacy Boards were in a stronger position to monitor the physicians and pharmacists they licensed. Former management also believed that since Miami-Luken regularly provided the DEA with sales data for all its customers, the government would have advised them if they had concerns with sales to specific parties. Unfortunately, we now know that that is not enough, and as you know from the materials we provided this Committee last year, Miami-Luken has taken aggressive actions going back several years to strengthen its compliance efforts and suspicious order monitoring system.

Mr. Hammergren also provided background on his company. He said that over the last five years in particular, McKesson has successfully used the latest technology and the best available internal and external expertise to strengthen controls and to help reduce the risk that opioids and other controlled substances could be diverted to abuse or other illegitimate uses. And since 2008,

McKesson has blocked the shipment of over a million orders for controlled substances nationwide. In 2014, McKesson terminated the Mount-Gay-Shamrock pharmacy's controlled substance access after observing a suspicious volume of hydrocodone and alprazolam ordered by the pharmacy and because of concerns about some of the physicians whose prescriptions the pharmacy was continuing to fill. Over the last five years, McKesson has invested millions of dollars in enhancing our Controlled Substance Monitoring Program ("CSMP"), which provides ongoing review and monitoring of the pharmacies and hospitals that purchase from McKesson to help mitigate the risk that controlled substances, including opioids, are diverted, abused and other inappropriate uses. As a result of these ongoing efforts, from 2008 through 2017, McKesson blocked and reported to DEA over one million suspicious orders nationwide. The company is working to develop a prescription safety alert system that would give real-time red flags based on a patient's nationwide prescription history.

Mr. Barrett summarized the operations of Cardinal Health. He said that his organization recognizes its role as a pharmaceutical wholesale distributor meaning it has a dual responsibility—to ensure that prescription medications are available for prescribers and their patients when needed, while working to limit the potential for those prescription medications to fall into the wrong hands. Cardinal Health has made available Narcan, an opioid overdose reversal medication, free-of-charge to first responders and law enforcement. They have also continued to enhance our anti-diversion program and have entered into settlements with the DEA and the state of West Virginia.

Mr. Collis emphasized that AmerisourceBergen Drug Corporation's distribution role in the system is vital, yet limited in many ways. Prescription opioids represent less than 2% of AmerisourceBergen's annual revenue. Further, as a wholesale distributor, AmerisourceBergen Drug Corporation does not control how any medications we deliver are prescribed, dispensed, or ultimately used. AmerisourceBergen Drug Corporation has refused to service and has terminated service to hundreds of pharmacies that it identified as problematic, including some of the pharmacies in West Virginia that news reports have claimed were diverting opioids. Since at least the 1980s, AmerisourceBergen Drug Corporation has had in place a system to monitor the orders it receives (the "Order Monitoring Program," or "OMP"). We worked with the DEA to enhance the system in 1998, and again in 2007, and have continually reviewed and improved it, including a comprehensive 2015 revision to build on current data, responding to trends in prescription drug abuse, and adopt improved technological capabilities, including data-driven analytical tools. The OMP's innovative program uses sophisticated technology to test every order of controlled substances that AmerisourceBergen Drug Corporation receives. Orders that the system identifies as "of interest" are held electronically and investigated, and shipment is automatically blocked until the investigation is complete and the order is determined to be appropriate. If the order is deemed suspicious after that review, the order is reported to the DEA and is not shipped. Using the OMP, AmerisourceBergen Drug Corporation reported and refused to ship more than 800 such orders for oxycodone and hydrocodone from West Virginia from 2008 to 2016.

Mr. Smith said that H.D. Smith was a family-owned wholesaler for more than 60 years, and was recently acquired by Amerisource Bergen. H.D. Smith was only one part of a complex supply chain, and we could not see all the information up and down the chain that could flag a potential problem. As a wholesale distributor, H.D. Smith could not second-guess physicians' prescribing decisions, and could not itself assess the medical needs of the patients of those prescribing physicians. In addition to taking physical security measures to safeguard against theft and diversion of opioids and other medicines, H.D. Smith developed and maintained a robust anti-diversion program, which was designed to identify potentially suspicious orders. That program came to include, among other components, a controlled substance order monitoring program, focused investigations conducted by an experienced group of former law enforcement and drug diversion investigators, and comprehensive customer and sales force anti-diversion training. We also performed extensive due diligence on prospective new customers before allowing them to purchase controlled substances, and those due diligence measures continued to evolve over time and continued throughout our relationships with customers. He continued to detail the steps H.D. Smith took in compliance with DEA's expectations.

Questions and Answers

Subcommittee Chairman Harper asked if the witnesses believed the actions their companies took contributed to the opioid epidemic. **Mr. Barrett** said no. **Dr. Mastandrea** said yes. **Mr. Hammergren** said no. **Mr. Smith** said no. **Mr. Collis** said no. **Mr. Barrett** refused to acknowledge that his company had past failings in the diversion of opioids. On the same question, **Dr. Mastandrea** said yes, **Mr. Hammergren** said no, **Mr. Smith** said no, and **Mr. Collis** said no.

Subcommittee Ranking Member DeGette asked the witnesses to respond to the fact that each company has a duty under the CSA that duty to make sure controlled substances are distributed responsibly. All witnesses agreed. She questioned **Dr. Mastandrea** directly about opioids sent by his company to a small pharmacy in Kermit, WV. She thanked him for his honesty. She then asked **Mr. Hammergren** to explain why McKesson gave only a two-page document when asked by the Committee for Sav-Rite's due diligence file. He refused to agree that it's not sufficient documentation.

Chairman Walden asked **Mr. Hammergren** if he know the average number of hydrocodone pills distributed to Sav-Rite. He didn't know. **Chairman Walden** said the number of pills distributed was 36x the monthly threshold set by McKesson. **Mr. Hammergren** said the Sav-Rite relationship wasn't properly managed. **Chairman Walden** asked what happened to allow this over-distribution. **Mr. Hammergren** said new automated systems were put in place after the Sav-Rite discovery. McKesson can't see prescriber information, so they have to determine suspicious orders based on quantity.

Ranking Member Pallone asked how it can be ensured adequate systems are put in place to avoid over-distribution in places like Kermit, etc. **Dr. Mastandrea** said that his company has made several changes, including now having a full time compliance officer, investigator who

makes site visits, etc. **Ranking Member Pallone** then asked **Mr. Barrett** what specific changes were made to his company's compliance program. **Mr. Barrett** said that his company's systems now reflect new information.

Rep. Barton asked if the opioid crisis is one problem that can be solved. All witnesses said yes, but with qualifications**. Rep. Barton** then asked the witnesses what percentage of responsibility their companies have for the crisis. The witnesses refused to name a percentage, but agreed that their companies and industry share the blame.

Rep. Castor asked how Cardinal estimated what amount of opioids was appropriate for a pharmacy. **Mr. Barrett** said that the evolution was from looking a system that established the legitimacy of a pharmacy to what was actually happening in terms of orders. She continued to push back on Cardinal's operations.

Vice Chairman Griffith asked **Mr. Hammergren** about the DOJ settlement. He said that failing to live up to the 2008 agreement doesn't show a high level of commitment/engagement. **Mr. Hammergren** disagreed.

Rep. Schakowsky asked the witnesses if their companies had measures in place to comply with CSA. The witnesses said yes. **Mr. Smith** said that DEA's expectation continually changed. **Mr. Hammergren** was asked questions on McKesson's profits net-per-unit; he answered that manufacturers set prices and he has no knowledge of net-per-unit profits.

Rep. Burgess asked **Mr. Smith** what the DEA does with information on suspicious orders. **Mr. Smith** said that he doesn't know. He added that for the most of his career, interactions with DEA were very purposeful and collaborative. But, over the past few years, DEA has become evasive and difficult to get feedback from them.

Rep. Tonko asked **Mr. Barrett** about a memo written by a Cardinal employee on two doctors who were running pill mills in 2008. **Mr. Barrett** said that he regrets not acting sooner.

Rep. Brooks asked about Family Discount Pharmacy. **Mr. Smith** was asked about an email from a H.D. Smith employee discussing Dr. Hoover's 51% hydrocodone scripts being filled by Family Discount Pharmacy. **Mr. Smith** said he isn't sure when his company reported this information to the DEA.

Rep. Ruiz said that eliminating mental health coverage as an essential health benefit is moving backwards in regards to solving the opioid crisis. He lambasted the witnesses' companies for showing one plan on paper and implementing something else entirely. **Rep. Ruiz** asked **Dr. Mastandrea** what process is in place to identify suspicious orders. **Dr. Mastandrea** said that there is an automated, electronic system that looks at several factors to determine and flag suspicious orders for further review.

Rep. Walberg asked if Amerisource Bergen's investigations focus on the percentage of controlled substances particular suspicious pharmacies fill. **Mr. Collis** agreed. If the pharmacy was servicing a pill mill doctor, Amerisource wouldn't service that pharmacy.

Rep. Walters asked **Mr. Barrett** about Cardinal's adjustment of a pharmacy's threshold to allow for distribution of more opioids. **Mr. Barrett** said that today, if an order reaches its threshold, it simply stops. In the past, the thresholds should have been set differently. He said that he has no reason to question the good intent of professionals who had to make a determination on the explanations given by pharmacies to increase their thresholds.

Rep. Carter asked the witnesses if they knew what DEA does with reported information. The witnesses said they didn't know. **Rep. Carter** said that hydrocodone became a C2 drug in 2014. He asked why it took so long to reschedule hydrocodone.

Rep. Costello asked **Mr. Barrett** why Cardinal is citing different community figures now that it initially did (more limited scope). **Mr. Barrett** said that rural pharmacies tend to serve a larger area. **Rep. Costello** said Family Discount produced a drug dispensing report for Cardinal.

Rep. Blackburn asked if anyone has personally met with families who have lost loves ones to the opioid crisis. All witnesses except **Mr. Collis** answered yes. She then asked if they have employees in treatment/recovery and if the company's insurance covers this. **Mr. Barrett** said his coverage covers behavioral issues. **Dr. Mastandrea** said yes and insurance covers substance abuse issues. **Mr. Hammergren** said yes and yes. **Mr. Smith** said he didn't know as did **Mr. Collis.** All witnesses agreed that they knew these drugs had side effects. She asked for them to submit to the record how often their systems flag a bad pharmacy.

Rep. Lance asked **Dr. Mastandrea** about raising pharmacy thresholds for oxycodone. **Dr. Mastandrea** said he wasn't aware of the numbers **Rep. Lance** was asking for. **Rep. Lance** asked him to prepare real answers and submit them for the record.

Rep. McKinley expressed his anger at the witnesses companies for shirking responsibility for the crisis. He asked what the punishment is to fit the crime of pushing pills without due diligence. He said he wants the companies to feel ashamed about their roles in this crisis.

Rep. Johnson asked the witnesses where to go from here. **Dr. Mastandrea** said that he finds it unusual that his company would sell directly to a physician and that the physician was a dispensing physician. He said his company should have never supplied to her.

Rep. Bilirakis asked if the companies verify if pharmacies were cut off from other distributors before bringing them on as new customers. **Mr. Barrett** said they can't know for sure. All witnesses agreed that it's difficult to get accurate information on that.

The Subcommittee was adjourned.